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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,803	07/17/2003	Kenneth A. Browne	GP131-03.UT	5941

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EXAMINER	
PANARO, NICHOLAS J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,803	BROWNE, KENNETH A.	
	Examiner	Art Unit	
	Nicholas J. Panaro	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 19 are drawn to a device for amplifying and detecting a target nucleic acid classified in class 435, sub class 287.2, for example.

II. Claims 10-18 and 20 are drawn to a method of making a device for amplifying and detecting a target nucleic acid classified in class 435, sub class 6, for example.

III. Claims 21-31 are drawn to a method of chemically bonding a biomolecule to a solid support classified in class 536, sub class 25.3, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the device could be fabricated by synthesizing the immobilized oligonucleotides *in situ* using photolithographic masks (e.g., U.S. Patent 5,474,796). The search for the product would not necessarily yield art pertaining to the process of making.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of Group I is directed to a device for amplifying and detecting a target nucleic acid whereas Group III is directed to a method of chemically bonding a biomolecule to a solid support. The device of Group I is not required to conduct the method of Group III nor is the method of Group III required to fabricate the device of Group I.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention of Group II is directed to a method of making a device for amplifying and detecting a target nucleic acid whereas Group III is directed to a method of chemically bonding a biomolecule to a solid support. The method of Group II is not required to conduct the method of Group III nor is the method of Group III required to conduct the method of Group II.

During a telephone conversation with Michael Gilley on November 3, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-9 and 19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-18 and 20 and 21-31 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under CFR 1.17(i).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as exemplified by their different classification, restriction for examination purposes as indicated is proper. Further, a search for the inventions of both groups would not be co-extensive because a search indicating the process is novel or nonobvious would not extend to a holding that the product itself is novel or nonobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to the final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b), " 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 19, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

For purposes of examination, the examiner interprets "probe" as an intended use of an oligionucleotide. Therefore, the term "oligonucleotide" may be substituted for the term "probe".

For purposes of examination, "substantially uniformly" will be interpreted as meaning a majority of oligonucleotides immobilized on a support surface are immobilized in any pattern.

For purposes of examination, the examiner interprets "positive control nucleic acid" as an intended use of a nucleic acid. Therefore, any target nucleic acid can be used as a "positive control nucleic acid".

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al (U.S. Patent 5,656,462; issued August 12, 1997; cited in IDS).

Regarding claim 1, Keller et al teach a device for detecting a target nucleic acid, comprising: a solid support having a surface (column 8, lines 2-10); at least one species of oligonucleotide immobilized

substantially uniformly (as defined above), i.e., covalently bound to carboxyl residues (column 10, lines 34-58) over said surface, thereby defining a field of oligonucleotides, said at least one species of oligonucleotide being complementary to a first strand of said target nucleic acid because every oligonucleotide is complemetary to some other nucleic acid (column 8, lines 11-18; column 9, lines 12-18 and 22-26); and a plurality of hybridization probes immobilized to the solid support at discrete positions, i.e., specific binding to carboxyl residues (column 10, lines 34-58) within said field of immobilized oligonucleotides (column 8, lines 34-37).

Regarding claim 2, Keller et al teach a said comprising a material selected from the group consisting of glass and plastic (column 8, lines 2-10).

Regarding claim 3, Keller et al teach at least one species of oligonucleotide immobilized uniformly (as defined above) i.e., covalently bound to carboxyl residues (column 10, lines 34-58) over said surface is immobilized covalently (column 8, lines 34-37; column 9, lines 49-54; column 9, line 64 – column 10, line 4).

Regarding claim 4, Keller et al teach a plurality of hybridization probes immobilized to the solid support are immobilized covalently (column 8, lines 34-37; column 9, lines 49-54; column 9, line 64 – column 10, line 4).

Regarding claim 5, Keller et al teach at least one species of oligonucleotide and said plurality of hybridization probes are immobilized covalently (column 8, lines 34-37; column 9, lines 49-54; column 9, line 64 – column 10, line 4).

Regarding claim 6, Keller et al teach the hybridization of a target nucleotide (i.e., polyadenylated mRNA) to immobilized oligonucleotides (i.e., 30-100-mer polynucleotide sequence) and subsequent synthesis of a complementary opposite strand (i.e., cDNA of an mRNA-cDNA hybrid) from said target

nucleotide via reverse transcription (column 13, lines 47-56). Since the reaction takes place in solution both the mRNA and the immobilized cDNA are soluble.

Regarding claim 7, Keller et al teach a plurality of self-reporting probe, for example, radionuclides, biotin (column 11, lines 62-67).

Regarding claim 9, Keller et al teach at least one species of oligonucleotide immobilized uniformly (as defined above) over said surface comprises a promoter sequence for an RNA polymerase (column 7, lines 59-63; column 8, lines 34-36; column 9, lines 27-29).

Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al (WO 01/48242; published July 5, 2001; cited in IDS).

Regarding claim 1, Hu et al teach a device (pg. 20, paragraph 0071) for amplifying and detecting a target nucleic acid, comprising: a solid support having a surface (claim 17, part a, pg. 38); at least one species of oligonucleotide immobilized substantially uniformly, i.e., immobilized in discrete areas according to a predetermined pattern (pg. 20, paragraph 0071) over said surface, thereby defining a field of oligonucleotides, said at least one species of oligonucleotide being complementary to a first strand of said target nucleic acid (claim 17, part a, pg. 38); and a plurality of hybridization probes immobilized to the solid support at discrete positions within said field of immobilized oligonucleotides i.e., immobilized in discrete areas according to a predetermined pattern (pg. 20, paragraph 0071).

Regarding claim 19, Hu et al teach a kit (pp.27-28, paragraph 0090) comprising a device (pg. 20, paragraph 0071) for amplifying and detecting a target nucleic acid, a soluble oligonucleotide primer (pg. 28, paragraph 0090), and a positive-control nucleic acid (as defined above) amplifiable in a nucleic acid amplification reaction (pg. 27, paragraph 0090) using said at least one species of oligionucleotide primer

immobilized uniformly (as defined above) over said surface (pg. 27, paragraph 0090) in combination with said soluble oligonucleotide (pg. 28, paragraph 0090).

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated Liu et al (Anal. Chem. Vol. 71, pp. 5054-5059, 1999; cited in IDS).

Regarding claim 1, Liu et al teach a device (Abstract) for detecting a target nucleic acid, comprising: a solid support having a surface, i.e., silica optical fiber (pg. 5055, paragraph 4); at least one species of oligonucleotide immobilized substantially uniformly, i.e., immobilized on the etched portion of the fiber (pg. 5055, paragraph 4; Figure 1) over said surface, thereby defining a field of oligonucleotides, said at least one species of oligonucleotide being complementary to a first strand of said target nucleic acid (pg. 5056, paragraph 3; Figure 1); and a plurality of hybridization probes immobilized to the solid support at discrete positions within said field of immobilized oligonucleotides i.e., immobilized on the etched portion of the fiber (pg. 5055, paragraph 4; Figure 1).

Regarding claim 8, Liu et al teach probes comprising a fluorophore moiety, e.g., a molecular beacon labeled with tetra methylrhodamine (pg. 5055, paragraph 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas J. Panaro whose telephone number is (571) 272-0778. The examiner can normally be reached on Monday - Friday 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NJP

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